

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended
Accusation:

R&W PHARMACY SERVICES, INC.
165 B Pointdexter Avenue
Moorpark, CA 93021
PATTI JO REED, President/Treasurer/CEO
ARTHUR HOWARD BERGER, Secretary

Original Pharmacy Permit No. PHY 43143

And

ARTHUR HOWARD BERGER
30061 Torre Pines Place
Agoura Hills, CA 91301
Pharmacist-in-Charge

Original Pharmacist License No. RPH 30997

Respondents.

Case No. 2279

OAH No. L2003110259

PROPOSED DECISION

Michael A. Scarlett, Administrative Law Judge, Office of Administrative Hearings (OAH), heard this matter on June 13, 14, and 15, 2005, in Los Angeles, California.

Joseph N. Zimring, Deputy Attorney General, represented Complainant.

Robert L. Esensten, Attorney at Law, represented Respondent R&W Pharmacy and the interest of Patti Jo Reed. Donald B. Brown, Attorney at Law, represented Respondent Arthur Howard Berger.

Oral and documentary evidence was received and the record was held open until August 5, 2005, to allow the parties to submit written closing and reply briefs. The parties

timely submitted closing briefs and reply briefs and the matter was submitted on August 5, 2005.¹

FACTUAL FINDINGS

1. Patricia F. Harris (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On October 7, 1997, the Board issued Original Pharmacy Permit No. PHY 43143 to Respondent R&W Pharmacy Services, Inc. (hereinafter R&W Pharmacy) to do business at 165 B Poindexter Avenue, Moorpark, California 93021. R&W Pharmacy was licensed by the Board as a corporation. From October 7, 1997, through December 31, 1999, the corporate officers were Peter B. Wollons, President, and Patty Jo Reed, Vice President. On December 31, 1999, Reed became the President, Treasurer, and Chief Executive Officer of R&W Pharmacy, and Respondent Arthur Howard Berger (Respondent Berger) became the Secretary of the company. Original Pharmacy Permit No. PHY 43143 was in full force and effect at all times relevant to the charges brought herein and was scheduled to expire on October 1, 2005, unless renewed.²

3. On July 29, 1977, the Board issued Original Pharmacist License No. RPH 30997 to Respondent Berger. Respondent Berger was the Pharmacist-in-Charge (PIC) for R&W Pharmacy from October 7, 1997, through October 24, 2004. Respondent Berger's pharmacist license was in full force and effect at all times relevant to the charges in the First Amended Accusation and will expire on April 30, 2006, unless renewed.

4. On the first day of hearing, the Board informed OAH that it was withdrawing its allegations in the First Amended Accusation against Respondent Berger pursuant to a settlement agreement reached between the parties on May 17, 2005. Respondent Berger agreed to testify at the hearing as a condition of his settlement agreement. He did not admit any of the allegations in the First Amended Accusation as a condition of the settlement agreement and he agreed to pay \$6,000.00 to the Board for the cost of investigation and enforcement of this case.

5. R&W Pharmacy operated as a "closed door" (closed shop) pharmacy from October 7, 1997 until May 31, 2005. As a closed door pharmacy, R&W Pharmacy provided

¹ The Board filed its closing brief on July 25, 2005, which was marked for identification as Complainant's Exhibit 17. Respondent R&W Pharmacy filed its closing brief on July 22, 2005, which was marked for identification as Respondent's Exhibit AA. The Board filed its reply brief on August 5, 2005, which was marked for identification as Complainant's Exhibit 18. Respondent filed its reply brief on August 5, 2005, which was marked for identification as Respondent's Exhibit BB.

² The Board's First Amended Accusation named R&W Pharmacy and Arthur Howard Berger as the Respondents in the case. Although Patty Jo Reed was identified as the President/Treasurer/CEO of R&W Pharmacy in the accusation, Reed was not licensed by the Board. R&W Pharmacy's Pharmacy Permit No. PHY 43143 and Arthur Howard Berger's pharmacy license number RPH 30997 are the only licenses subject to discipline under the Board's First Amended Accusation. Accordingly, Patti Jo Reed is not considered a Respondent in this matter.

drug services to institutional health care providers such as nursing homes, mental health facilities, and jail facilities. The pharmacy was not open to the public-at-large like a typical pharmacy. In 1998, R&W Pharmacy entered into three separate "membership agreements" with group purchasing organizations to purchase pharmaceutical products at preferred group pricing rates: GeriMed, Managed Health Care Associates, Inc. (MHA), and AmeriNet/Intermountain Health Care (AmeriNet/IHC). All three of the group purchasing agreements restricted R&W Pharmacy to purchasing pharmaceutical products from these organizations for its "own use" for sale to its institutional clients.

6. The GeriMed purchasing agreement specifically provided that all purchases made by R&W Pharmacy under the agreement were to be for R&W Pharmacy's "own use." The term "own use" was specifically limited under the GeriMed agreement to: (1) dispensing drugs to inpatients or emergency patients for treatment at the facilities serviced by R&W Pharmacy; (2) dispensing drugs to former patients upon their discharge as take-home prescriptions or supplies necessary for a limited and reasonable time as continuation of treatment; (3) dispensing drugs to R&W Pharmacy employees or employees of the facilities serviced by R&W Pharmacy for their own use or the use of their dependents; or (4) dispensing drugs to a staff member or physician in a facility serviced by R&W Pharmacy for his or her personal use, or for the use of his or her dependents. The GeriMed agreement further provided that R&W Pharmacy could not buy, distribute, sell, transfer, or use group purchased pharmaceutical products or distribute these products in any manner contrary to the terms and conditions in the agreement. The GeriMed agreement identified only R&W Pharmacy as a party to the agreement and indicated that R&W Pharmacy serviced 107 beds at the facilities the pharmacy serviced.

7. Similarly, the MHA purchasing agreement provided that the benefits of the purchasing organization were for "closed shop" healthcare providers for their "own use." The MHA contract specifically stated that its prices were intended for its "Members" and its products were to be dispensed by the Member to its "closed shop long term care facilities." The MHA agreement prohibited R&W Pharmacy from selling, wholesaling or otherwise transferring any product purchased under the agreement to any other person or entity not identified in the agreement, or except as provided by law.

8. In November 1998, the Board received a complaint that alleged R&W Pharmacy was buying in excess of the drugs required for their own needs. The complaint alleged that drugs were being purchased in excess of that needed to supply the pharmacy's close shop pharmacy clients. The complaint further alleged that R&W Pharmacy was wholesaling drugs to buyers other than the clients specified in their group purchasing contracts.

9. On June 16, 1999, the Board initiated an investigation and conducted a site visit at R&W Pharmacy. Robert Venegas, a Board Inspector, conducted the inspection during which Respondent Berger was present. Venegas informed Berger that he was there to examine the pharmacy's records. Berger stated that all of the pharmacy's records were kept off premises and were unavailable for inspection at that time. Venegas advised Berger that

the Board required all records to be kept on the premises unless a waiver had been issued by the Board. Venegas completed his inspection report and ordered R&W Pharmacy to produce the pharmacy's records of acquisitions from January 1, 1999 until June 16, 1999. Venegas also requested Berger to produce copies of R&W Pharmacy's group purchasing contracts or "Bid Contracts" to the Board within 72 hours.

10. On June 25, 1999, Respondent Berger, on behalf of R&W Pharmacy, submitted a letter stating that the documents requested by the Board were enclosed for the Board's review. Berger provided the Board with copies of the pharmacy's prescription log, some invoices from wholesalers, and three buying group contracts. The prescription log indicated that the total cost of prescriptions dispensed by R&W Pharmacy from January 1, 1999, until June 16, 1999, was \$520,770.97. Berger provided copies of the invoices for \$520,770.97 in drug purchases by R&W Pharmacy. Of that total, \$485,164.71 was for invoices for purchases from McKesson Drug. Consequently, the Board requested McKesson Drugs to provide copies of all of their invoices to R&W Pharmacy for the period from January 1999 until June 1999.

11. On August 25, 1999, McKesson Drug provided the Board with copies of invoices submitted to R&W Pharmacy from January 1, 1999 until June 16, 1999. The invoices indicated that R&W Pharmacy had purchased \$6,968,612.84 in drugs from McKesson Drugs during this period, almost \$6,500,000 in purchases more than was reported by Berger in the documents supplied by R&W Pharmacy to the Board on June 25, 1999. Based on the invoices produced by McKesson Drug, the Board concluded that R&W Pharmacy had failed to produce records of \$6,483,448.13 in drug purchases from McKesson Drugs for the relevant period addressed by the June 16, 1999 inspection.

12. On November 12, 1999, the Board issued a Notice of Violation to R&W Pharmacy alleging that the pharmacy had failed, neglected, or refused to provide all of the records of acquisition and dispositions of drugs as requested by the Board's inspector in June 1999. The Board further alleged that a substantial inventory of dangerous drugs was unaccounted for by R&W Pharmacy and required the pharmacy to provide a detailed explanation of the missing McKesson Drug purchase invoices.

13. On December 14, 1999, R&W Pharmacy's attorney, Robert Esensten, responded to the Board's Notice of Violation by letter. Esensten acknowledged that Berger had not provided all of R&W Pharmacy's records as requested in June 1999, but maintained the records had always been "available" for inspection by the Board. Esensten claimed that Respondent Berger was the PIC for R&W Pharmacy and was fully responsible for the daily operation of the pharmacy.

14. Esensten further informed the Board that R&W Pharmacy had been purchasing pharmaceutical products for itself and its "wholly owned subsidiary," Montana Pharmaceutical Services, Inc. (MPS), located in Kalispell, Montana. Esensten provided the Board with a complete set R&W Pharmacy's drug records including copies of invoices from R&W Pharmacy to MPS from January 1999 until June 1999. The MPS invoices totaled

approximately \$6,500,000 and represented over 90% of the drugs purchased by R&W Pharmacy through its group purchasing contracts from January 1999 until June 1999. The MPS records did not include invoices detailing how MPS resold or dispersed the pharmaceutical products purchased from R&W Pharmacy.

15. MPS was licensed by the State of Montana on December 7, 1998. The license was issued to "Montana Pharmaceutical Services, Inc.", as the pharmacy, and "Montana Pharmaceutical Services, Inc. (Corporation)" as "owner" of the pharmacy. Patti Jo Reed and Peter Woolens owned equal 50% shares of MPS during the relevant time period of the Board's Accusation, from January 1999 until June 1999. Respondent Berger also served as the PIC for MPS during the relevant period in the Board's investigation. Respondent Berger and Patti Jo Reed testified that MPS operated as a closed shop pharmacy which provided pharmaceutical products to institutional facilities such as jails and nursing homes. However, neither produced copies of any group purchasing contracts to support this fact. On December 31, 1999, Peter Wollens sold 49% of his shares in MPS to Patti Jo Reed, leaving Wollens with a one percent ownership interest in the corporation. At that time, Patti Jo Reed owned 99% of MPS. On November 1, 2002, Patti Jo Reed sold MPS to Laura Daugharty, R.Ph., who became the sole owner and the pharmacists-in-charge of the pharmacy.

16. On June 7, 2000, the Board issued a second Notice of Violation to R&W Pharmacy alleging that R&W Pharmacy had unlawfully acted as a wholesaler of dangerous drugs without obtaining a license from the Board when it sold pharmaceutical products to MPS between January 1999 and June 1999. On June 9, 2000, Robert L. Esensten responded to the Board's notice of violation requesting the Board to provide a factual basis upon which the violation was based. Esensten stated that his client could not respond to the Board's notice of violation without receiving additional information regarding the allegations. The notice of violation referenced the Board's case number 98-16900, which was the case number assigned to the R&W Pharmacy investigation. The Board did not respond to Esensten's June 9, 2000 letter. There was no communication between the Board and R&W Pharmacy from June 2000 until the Board issued its September 29, 2003 Accusation.

17. The evidence established that R&W Pharmacy failed to provide all of its pharmaceutical records to the Board in June 1999 when requested by the Board's investigator. It was not until December 1999, after the Board had obtained proof of additional drugs purchased by R&W Pharmacy from McKesson Drug, that R&W Pharmacy provided the Board with copies of the additional records. These invoices totaled almost \$6,500,000 in drug purchases that were later resold by R&W Pharmacy to MPS in Montana. R&W Pharmacy knowingly and falsely represented to the Board in Respondent Berger's June 17, 1999 letter that it had provided all of the drug invoices for the period requested by the Board.

18. The evidence did not establish that MPS was a "wholly owned subsidiary" of R&W Pharmacy. Montana licensing records, nor the records of the sale of MPS, indicate that MPS was ever owned by, or was a wholly owned subsidiary of, Respondent R&W Pharmacy. MPS's Montana pharmacy license indicates that MPS was a pharmacy owned by

the MPS Corporation, not R&W Pharmacy. The sales contract for MPS was between Patti Jo Reed and Laura Daugharty and indicated that Reed, not R&W Pharmacy, was selling her rights and stock interest in MPS to Daugharty. There is no evidence that R&W Pharmacy received any of the sales proceeds from the sale of MPS to Daugharty in November 2002. The sales contract made no reference to a wholesale agreement between R&W Pharmacy and MPS or that such an agreement could continue for any period of time. R&W Pharmacy's group purchasing agreements neither lists MPS as a subsidiary of R&W Pharmacy or as a closed shop client of R&W Pharmacy. Although Patti Jo Reed had an individual ownership interest in both R&W Pharmacy and MPS, this did not render MPS a subsidiary of R&W Pharmacy.

19. The evidence established that between January 1999 and June 1999, R&W Pharmacy resold to MPS almost \$6,500,000 in pharmaceutical products purchased under its group purchasing agreements. MPS, an out-of-state pharmacy, was not identified as a party in R&W Pharmacy's group purchasing agreements. Thus, R&W Pharmacy's sale of the pharmaceutical products to MPS violated its group purchasing contracts which required that R&W Pharmacy use any drugs purchased at preferential pricing under the contracts for its "own use." R&W Pharmacy's violation of its group purchasing contracts and its failure to initially disclose the MPS transactions to the Board evidences dishonesty and deceit and thus constitutes unprofessional conduct. R&W Pharmacy's resale of the pharmaceutical products to MPS also constituted wholesaling large quantities of dangerous drugs. R&W Pharmacy was not licensed by the Board to wholesale pharmaceutical products and thus is subject to discipline by the Board for this conduct.

20. On January 15, 2004, Robert Esensten wrote a letter to Laura Daugharty at MPS requesting documents pertaining to MPS's operations from the period from January 1999 until June 1999. Esensten requested documents related to purchases of pharmaceuticals by MPS from R&W Pharmacy, evidence of prescriptions filled by MPS, a statement from MPS that it did not have its own wholesaler of pharmaceutical products, and evidence of its use of pharmaceutical products purchased from R&W Pharmacy. On March 15, 2004, Daugharty responded by letter that MPS had no records of purchases from R&W Pharmacy because the records had been destroyed.

21. The Board certified that it incurred \$14,569.75 in costs prior to the filing of its Accusation in September 2003 and \$26,094.25 in costs after the Accusation was filed, for a total amount \$40,664.00. The Board's inspector cost was \$6,093.75 which included 93.75 hours at \$65.00 per hour. The legal analyst's cost was \$1,632.25 which included 27.75 hours, with 23.50 hours being billed at \$53.00 per hour and 4.25 hours being billed at \$91.00 per hour. The Attorney General's cost was \$32,938.00 which included 258 hours at various hourly rates per hour.

22. This Administrative Law Judge finds that the Board's cost were reasonable given the more than three years involved in investigating this case and the fact that a significant portion of the investigation involved an out-of-state pharmacy. Pursuant to Business and Professions Code section 125.3, the Board shall be awarded the reasonable cost

of investigation and enforcement of this case in the amount of \$40,664.00. As a result of a settlement agreement between Respondent Arthur Howard Berger and the Board, Respondent Berger agreed to reimburse the Board \$6,000.00 in costs. Accordingly, the Board's cost recovery as to Respondent R&W Pharmacy is reduced to \$34,664.00.

LEGAL CONCLUSIONS

1. Business and Professions Code section 4301 provides that the "Board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake." (Bus. & Prof. Code § 4301.) Unprofessional conduct includes, but is not limited to, (f) "the commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is a felony or misdemeanor or not"; or (g) "knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts"; or (j) "the violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs"; or (o) "[v]iolating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board." (Bus. & Prof. Code § 4301, subds. (f), (g), (j) and (o).)

2. Cause exists to discipline Respondent R&W Pharmacy's Original Pharmacy Permit Number PHY 43143, pursuant to Business and Professions Code sections 4301, subdivisions (g), (j) and (o), and 4081, subdivisions (a) and (b), and 4332, for unprofessional conduct in that Respondent failed to maintain records of acquisition and disposition of drugs on the premises as required by law, and failed to produce records in a timely manner when requested by the Board in June 1999, by reason of Factual Findings 9 through 14, and 17.

Business and Professions Code section 4081, subdivisions (a) and (b) provide that:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with *Section 1200*) of the *Health and Safety Code* or under Part 4 (commencing with *Section 16000*) of *Division 9 of the Welfare and Institutions Code* who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

Section 4332 provides that “[a]ny person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.” (Bus. & Prof. Code § 4332.) “All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.” (Bus. & Prof. § 4105, subd. (a).) “The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.” (Bus. & Prof. § 4105, subd. (b).) “The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.” (Bus. & Prof. § 4105, subd. (c).)

Here, R&W Pharmacy failed to produce all of the records of acquisition and disposition of drugs for the pharmacy when requested by the Board’s investigator, Robert Venegas, on June 16, 1999. Respondent Berger informed Venegas that the records requested were not on the premises and that all of the invoices were kept off-site. Venegas issued an inspection report which demanded that R&W Pharmacy provide copies of all drug records and transactions from January 1999 to June 1999. Initially, R&W Pharmacy produced only a small portion of the records requested by the Board. Only after receiving a notice of violation from the Board, did Respondent produced the remainder of the requested records. The Board, through its own investigation, uncovered almost \$6,500,000 in drug purchases that R&W Pharmacy failed to produce records of upon request by the Board. Although R&W Pharmacy eventually produced all of the records requested, this was not done until six months after the Board’s inspection and demand for documents. This delay was unreasonable and subjects R&W Pharmacy to discipline by the Board.

R&W Pharmacy argued at hearing that Respondent Berger was responsible for failing to produce the documents when requested by Venegas and that the records were always on the premises of the pharmacy. Berger, however, credibly testified that on June 16, 1999, the records were not on the pharmacy’s premises and that all of the McKesson Drug invoices were kept by Patti Jo Reed off-site. Furthermore, R&W Pharmacy remains ultimately liable for the conduct and actions of its PIC. Thus, even had Berger been responsible for not having the records on premise and failing to produce said records upon request by the Board, R&W Pharmacy is liable for Berger’s conduct. The PIC is responsible for a pharmacy’s compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. (Bus. & Prof. Code § 4113.) However, the owner, officer, and partner of a pharmacy are jointly responsible, with the PIC, for maintaining the records and inventory at the pharmacy. (Bus. & Code § 4081, subd. (b).)

3. Cause exist to discipline Respondent R&W Pharmacy's Original Pharmacy Permit Number PHY 43143, pursuant to Business and Profession Code sections 4301, subdivisions (f) and (o), and 4380, subdivision (a) for unprofessional conduct in that Respondent purchased drugs at preferential prices and resold the drugs to MPS for purposes other than Respondent's own use, by reason of Factual Findings 5 through 10, 15 through 20.

Business and Professions Code section 4380, subdivision (a) provides that the resale of drugs acquired at preferentially low prices under federal law is prohibited except in a few specified instances including: (1) when reselling for the entities' "own use" in providing pharmaceutical products to its closed shop clients and facilities; (2) when reselling to a purchaser who is also eligible for preferential pricing under federal law, and is controlled by, or is under common control with, the seller, and the purchases are for the purchaser's own use; and (3) when sold to a walk-in customer pursuant to a prescription, and the prescription sales represent less than 1 percent of the drugs purchased by the seller for its own use. (Bus. & Prof. Code § 4380, subd. (a).)

In *Abbott Laboratories Et. Al. v. Portland Retail Druggists Assoc. Inc.* (1976) 425 U.S. 1, the Supreme Court held that for purposes of the exemption under the Nonprofit Institutions Act, the term "own use" means "what reasonably may be regarded as used by the hospital in the sense that such use is a part of or and promotes the hospital's intended institutional operation in the care of persons who are its patients." (*Abbott Laboratories Et. Al. v. Portland Retail Druggists Assoc. Inc.* (1976) 425 U.S. 1, 14.) In *Abbott* the Supreme Court considered to what extent, and to who, a hospital could dispense drugs purchased through preferential pricing under the Nonprofit Institutions Act. The court concluded that the hospital's "own use" included dispensing drugs to inpatients, patients admitted to the emergency room, or to outpatients for use on the hospital premises. The hospital also could dispense drugs to these persons for "off-premise personal use" for a limited and reasonable period of time as a continuation of, or supplement to hospital treatment. "Own use" also included the hospital dispensing drugs to employees or students for their personal use, or the use of their dependents. Finally, "own use" included physician staff members for their personal use and that of their dependents. (*Abbott Laboratories Et. Al. v. Portland Retail Druggists Assoc. Inc.* (1976) 425 U.S. 1, 8-10.)

The evidence established that R&W Pharmacy resold almost \$6,500,000 in drugs to MPS between January and June 1999. These drugs had been purchased from McKesson Drug pursuant to a group purchasing contract governed by the Prescription Drug Marketing Act (PDMA). Under an exemption provided by the Nonprofit Institutions Act, Title 15 United States Code section 13c, R&W Pharmacy was allowed to purchase drugs at preferential pricing if those drugs were designated for its "own use." R&W Pharmacy's group purchasing contracts restricted the pharmacy to dispensing the drugs purchased under the contracts for its "own use" in supplying its "close shop" clients and facilities.

R&W Pharmacy violated the PDMA by reselling dangerous drugs to MPA. MPA was not identified as a closed shop client or facility in any of Respondent's group

purchasing agreements. The evidence showed that R&W Pharmacy resold only about \$500,000 of the \$7,000,000 in drugs it purchased during January 1999 to June 1999 to its identified closed shop clients and facilities. The remaining \$6,500,000 in purchases was resold to MPS, more than 90 percent of its total purchases during this period. There was insufficient evidence to establish that MPA was eligible for preferential pricing under federal law. Although Patti Jo Reed testified that MPS had its own group purchasing contracts as a closed shop pharmacy in Montana, the contracts were not offered at hearing. Moreover, if MPS had its own group purchasing agreements, it would have been unnecessary for R&W Pharmacy to provide MPS with over six millions in drug purchases for the period in question.

Abbott narrowly construed the term "own use" to mean the dispensing drugs to hospital patients, employees and staff, and employee and staff dependents. *Abbott* can not be reasonably read to expand the term "own use" to include an out-of-state pharmacy with no nexus to the group purchasing agreements under which R&W Pharmacy purchased drugs at preferential pricing. "Own use" under *Abbott* meant the reasonable use of the preferentially priced drugs by R&W Pharmacy as part of its "intended institutional operation" which was primarily the supplying of closed shop clients such as long term care facilities and jails. (See *Abbott Laboratories Et. Al. v. Portland Retail Druggists Assoc. Inc.*, *supra*, 425 U.S. 1, at p. 14.) R&W Pharmacy's three group purchasing agreements specifically referenced *Abbott* in defining the term "own use" for purposes of R&W Pharmacy's purchasing agreements. The agreements restricted R&W Pharmacy's use of the drugs purchased to the pharmacy's closed shop clients and facilities. None of the agreements mentioned MPS as a client, facility, or entity entitled to purchase drugs at preferential pricing under the group purchasing agreements.

Consequently, R&W Pharmacy's resale of drugs to MPS between January 1999 and June 1999 June was not for its "own use" as defined by the Nonprofit Institution Act and Respondent's group purchasing agreements. R&W Pharmacy knowingly violated its group purchasing agreements when it sold over 90 percent of the drugs purchased at preferential pricing to an entity not named as a party to the agreements and who was not a closed shop client served by R&W Pharmacy. The violation of the purchasing agreements and Respondent's initial failure to disclose this violation, evidences dishonesty and deceit and subjects R&W Pharmacy's license to discipline.

4. Cause exists to discipline Respondent R&W Pharmacy's Original Pharmacy Permit Number PHY 43143, pursuant to Business and Professions Code sections 4301, subdivision (o) and 4160, for unprofessional conduct in that Respondent sold almost \$6,500,000 in dangerous drugs to Montana Pharmaceutical Services, Inc. between January 1999 and June 1999 for use in that pharmacy even though Respondent was not licensed to do so, by reason of Factual Findings 5 through 10 and 15 through 20.

Business and Professions Codes section 4160, subdivision (a) provides "[a] person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board." Section 4160, subdivision (b) provides that

“[u]pon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.” “Every wholesale distributor in a State who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the State licensing authority in accordance with this part before engaging in wholesale distributions of prescription drugs in interstate commerce.” (21 C.F.R. § 205.4.)

R&W Pharmacy was not licensed by the Board to resell dangerous drugs and violated state law when it resold almost \$6,500,000 of pharmaceutical products to MPS in 1999. R&W Pharmacy, however, asserts that MPS was its “wholly owned subsidiary” and resale of the drugs to MPS was not violative of law. There is insufficient evidence to conclude MPS was a wholly owned subsidiary of R&W Pharmacy. R&W Pharmacy did not own MPS. In fact, MPS was licensed as a corporation in Montana without any reference to R&W Pharmacy as an owner of MPS. Although Patti Jo Reed owned stock interest in both R&W Pharmacy and MPS, this individual ownership interest does not render MPS a subsidiary of R&W Pharmacy.

Under California Corporation Code section 189, “subsidiary” of a specified corporation means a “corporation shares of which possessing more than 50 percent of the voting power are owned directly or indirectly through one or more subsidiaries by the specified corporation.” (Corp. Code § 189, subd. (a).) R&W Pharmacy did not own 50 percent or more of MPS. This conclusion is supported by the evidence in this case. The sale contract between Laura Daugharty and Patti Jo Reed did not reference R&W Pharmacy in any regard, including having a right to any portion of the sales proceeds or having any continued or prior relationship as a wholesaler for MPS.³

Finally, R&W Pharmacy argues that the Board failed to show it wholesaled drugs to MPS because there was insufficient evidence to show that R&W Pharmacy made a profit on the sale of the drugs to MPS. The Board need not show that R&W Pharmacy made a profit on the sale of the drugs to establish that Respondent acted as a wholesaler.

“‘Wholesaler’ means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or out-of-state distributor, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022....” (Bus. & Prof. Code § 4043, subd. (a).) “Wholesale distribution” means the distribution of prescription drugs to persons other than a consumer or patient. (21 C.F.R. § 205.3(f).) “Wholesale distributor means any one engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and wholesale drug

³ R&W Pharmacy also relies upon Business and Professions Code section 4126.5, subdivision (a), to assert that it was not unlawful for it to resale drugs to MPS. Section 4126.5 provides that a pharmacy may furnish dangerous drugs to another pharmacy under common control. (Bus. & Prof. Code § 4126.5, subd. (a).) Respondent’s reliance is misplaced, however, because Section 4126.5 was not enacted by the legislature until 2004, almost five years after the conduct at issue in this case. There is no authority to support Respondent’s assertion that it was entitled to resell millions of dollars worth of dangerous drugs to MPS in 1999.

warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.” (21 C.F.R. § 205.3(g).)

R&W Pharmacy’s conduct in reselling large quantities of dangerous drugs to MPS in 1999 constitutes wholesaling notwithstanding the absence of evidence showing it made a profit on the sales. That the record did not establish the amount of profit made by R&W Pharmacy is not dispositive. R&W Pharmacy engaged in the distribution of dangerous drugs to another entity who sold the drugs to third parties for purposes of filling prescriptions and other unidentified uses. Because R&W Pharmacy did not possess a wholesaler license issued by Board, R&W Pharmacy acted as a wholesaler without a license, and accordingly is subject to discipline for this conduct.

Defense of Laches

5. Respondent R&W Pharmacy contends the Board’s First Amended Accusation must be dismissed under the equitable doctrine of laches because the Board failed to file its original Accusation in a timely manner, thereby resulting in prejudice to Respondent when the Montana Pharmaceutical was unable to provide copies of invoices to its clients showing the disposition of the pharmaceutical products sold to it by R&W Pharmacy between January 1999 and June 1999. Montana Pharmaceutical allegedly destroyed the invoices after waiting the required three year period under Montana law for pharmacies to retain these documents. Respondent’s assertion is without merit.

OAH has the power to dismiss an administrative proceeding brought to revoke a state-issued license where there has been an unreasonable delay between the discovery of the facts constituting the reason for the revocation and the commencement of revocation proceedings, and where the licensee has been prejudiced by the delay. (*Medical Bd. Of California v. Superior Court* (1991) 227 Cal.App.3d 1458, 1462; *Gates v. Department of Motor Vehicles* (1979) 94 Cal.App.3d 921, 925.) However, dismissal should only be ordered where it is established that the agency’s delay in filing the accusation was unreasonable and resulted in prejudice to the licensee. (*Medical Bd. Of California v. Superior Court* (1991) 227 Cal.App.3d 1458, 1462; *Gates v. Department of Motor Vehicles* (1979) 94 Cal.App.3d 921, 925-926.) “It is not enough for a tribunal to simply find that a delay was, by virtue of the passage of time, unreasonable ‘as a matter of law’. That finding *must* be supported by substantial evidence of prejudice.” (*Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 815; *Mt. San Antonio Community College Dist. v. Public Employment Relations Bd.* (1989) 210 Cal.App.3d 178, 189.)

The burden of proving prejudice due to delay rests upon the party asserting the theory of laches. “Laches is an equitable defense which requires both unreasonable delay and prejudice resulting from the delay. The party asserting and seeking to benefit from the laches bar bears the burden of proof on these factors.” (*Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 815; *Mt. San Antonio Community College Dist. v. Public Employment Relations Bd.* (1989) 210 Cal.App.3d 178, 188.)

R&W Pharmacy failed to establish that the Board's issuance of its accusation constituted unreasonable delay and that prejudice resulted from the delay. The Board's investigator performed his initial site visit on June 16, 1999. In November 1999, after R&W Pharmacy had failed to produce the requested drug records, the Board issued a Notice of Violation alleging R&W Pharmacy had failed to produce all of its drug records as required by the Board. R&W Pharmacy did not produce the requested drug records until December 1999. After reviewing all of the records produced, in June 2000 the Board issued a second Notice of Violation alleging R&W Pharmacy engaged in wholesaling dangerous drugs without a wholesaler license. On September 29, 2003, the Board issued an accusation against R&W Pharmacy as a result of the Board's investigation.

Although the Board's issuance of the accusation in this case was over three years after the date of the last notice of violation, the Board is not required by statute to issue an accusation within a certain limitations period. Moreover, the evidence showed that R&W Pharmacy delayed its production of records and the Board's investigation involved acquiring information and records relating to an out-of-state entity, Montana Pharmaceutical Services. The Board's issuance of its accusation in this case was not unreasonably delayed.

However, even assuming the three-year period constituted an unreasonable delay in issuing the accusation, R&W Pharmacy failed to show a substantial prejudice resulted because of the delay. R&W Pharmacy essentially argues that the delay prevented it from obtaining MPS records relating to the use of drugs purchased from R&W Pharmacy. Because MPS was only required to maintain these records for a period of three years, the records relating to the investigation period had been destroyed. R&W Pharmacy asserts that these records would have shown that R&W Pharmacy did not resell pharmaceutical products purchased at a preferential price to MPS at a substantial profit.

R&W Pharmacy's argument must fail for two reasons. First, the Board placed R&W Pharmacy on notice that an investigation was being initiated in June 1999. In November 1999 and June 2000, the Board issued two separate notices of violations to R&W Pharmacy regarding the retention of records on the pharmacy's premises and wholesaling dangerous drugs to MPS without a license. Both of the notices indicated that the alleged violations may be forwarded to the district attorney for action or that an accusation could be issued by the Board seeking revocation or suspension of R&W Pharmacy's license. R&W Pharmacy was placed on substantial notice of the Board's possible disciplinary action. Thus, it should have known that records relating to its transactions with MPS were relevant and Respondent should have moved to secure the records from MPS to defend against these allegations.

Second, the evidence established that R&W Pharmacy sold MPS almost \$6,500,000 in pharmaceutical products. Although documents or invoices showing the disposition of these drugs by MPS were not available at hearing, such evidence is not relevant to the Board's allegations in its Accusation. The Board alleges that R&W Pharmacy resold large quantities of drugs to MPS without a wholesaler license. The Board does not

have to show that R&W Pharmacy made a profit on these drugs to establish this violation. The Board need only show that pharmaceutical products were sold to entities other than those identified in R&W Pharmacy's group purchasing agreements and that R&W Pharmacy did not have a wholesaler license to resell these drugs. Thus, records relating to MPS's disposition of drugs purchased from R&W Pharmacy are not relevant. Therefore, any prejudice to R&W Pharmacy as a result of MPS resale documents being unavailable for hearing is minimal. For a defense of laches, the prejudice must be substantial. (*Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 815.)

Cost Recovery

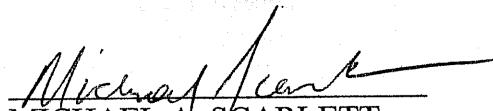
6. Pursuant to Business and Professions Code section 125.3, the Board shall be awarded its reasonable cost of investigation and enforcement of this case, by reason of Factual Findings 21 and 22.

ORDER

1. Respondent R&W Pharmacy's Original Pharmacy Permit Number PHY 43143, is hereby revoked by reason of Legal Conclusions 1 through 4, individually and jointly.

2. R&W Pharmacy is ordered to pay the Board's reasonable costs of investigation and enforcement in this case in the amount of \$34,664.00.

IT IS SO ORDERED this 10th day of August, 2006.


MICHAEL A. SCARLETT
Administrative Law Judge
Office of Administrative Hearings

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended
Accusation Against:

R & W PHARMACY SERVICES, INC.
165 B Pointdexter Avenue
Moorpark, CA 93021
PATTI JO REED, President/Treasurer/CEO
ARTHUR HOWARD BERGER, Secretary

Original Pharmacy Permit No. PHY 43143

and

ARTHUR HOWARD BERGER
30061 Torre Pines Place
Agoura Hills, CA 91301
Pharmacist-in-Charge

Original Pharmacist License
No. RPH 30997,

Respondents.

Case No. 2279

OAH No. L2003110259

DECISION

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy as its Decision in the above-entitled matter.

This Decision shall become effective on October 11, 2006

IT IS SO ORDERED September 11, 2006.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By



WILLIAM POWERS
Board President

rfm

BILL LOCKYER, Attorney General
of the State of California
GUS GOMEZ, State Bar No. 146845
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300 So. Spring Street, Suite 1702
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Attorneys for Complainant

**BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the Accusation Against:

Case No. 2279

R & W PHARMACY SERVICES, INC.
165 B Pointdexter Avenue
Moorpark, CA 93021
PATTI JO REED, President/Treasurer/CEO
ARTHUR HOWARD BERGER, Secretary

FIRST AMENDED ACCUSATION

Original Pharmacy Permit No. PHY 43143

And

ARTHUR HOWARD BERGER
30061 Torre Pines Place
Agoura Hills, CA 91301
Pharmacist-in-Charge

Original Pharmacist License No. RPH 30997

Respondent.

Complainant alleges:

PARTIES

1. Patricia F. Harris (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about October 7, 1997, the Board issued Original Pharmacy Permit No. PHY 43143 to R & W Pharmacy Services, Inc. (Respondent "R & W Pharmacy") to do

1 business at 165 B Pointdexter Avenue, Moorpark, CA 93021. The corporate officers from
2 October 7, 1997 through December 31, 1999 were Peter B. Wollons, President, and Patti Jo
3 Reed, Vice President. Board records further show that Patti Jo Reed has been President,
4 Treasurer, and Chief Executive Officer, and Arthur Howard Berger has been Secretary, since
5 December 31, 1999. The Original Pharmacy Permit was in full force and effect at all times
6 relevant to the charges brought herein and will expire on October 1, 2003, unless renewed.

7 3. On or about July 29, 1977, the Board issued Pharmacy Original
8 Pharmacist License No. RPH 30997 to Arthur Howard Berger to practice pharmacy. (Respondent
9 "Berger"). Respondent Berger has been the Pharmacist-in-Charge for Respondent R & W
10 Pharmacy, since October 7, 1997. The Original Pharmacist License will expire on April 30,
11 2004, unless renewed.

12 JURISDICTION

13 4. This Accusation is brought before the Board, under the authority of the
14 below mentioned statutes and regulations.¹

15 5. Section 4300 provides, in pertinent part, that every license issued by the
16 Board is subject to discipline, including suspension or revocation.

17 6. Section 4301 states:

18 "The board shall take action against any holder of a license who is guilty of
19 unprofessional conduct or whose license has been procured by fraud or misrepresentation or
20 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the
21 following:

22

23 "(f) The commission of any act involving moral turpitude, dishonesty, fraud,
24 deceit, or corruption, whether the act is committed in the course of relations as a licensee or
25 otherwise, and whether the act is a felony or misdemeanor or not.

26
27 1. All statutory references are to the Business and Professions Code (Code) unless
28 otherwise indicated.

1 “(g) Knowingly making or signing any certificate or other document that falsely
2 represents the existence or nonexistence of a state of facts.

3

4 “(j) The violation of any of the statutes of this state of the United States regulating
5 controlled substances and dangerous drugs.

6

7 “(o) Violating or attempting to violate, directly or indirectly, or assisting in or
8 abetting the violation of or conspiring to violate any provision or term of this chapter or of the
9 applicable federal and state laws and regulations governing pharmacy, including regulations
10 established by the board.”

11 7. Section 118, subdivision (b) of the Code, provides that the suspension,
12 expiration, or forfeiture by operation of law of a license does not deprive the Board of authority
13 or jurisdiction to institute or continue with disciplinary action against the license or to order
14 suspension or revocation of the license, during the period within which the license may be
15 renewed, restored, reissued or reinstated.

16 8. Section 4081 states, in pertinent part:

17 “(a) All records of manufacture and of sale, acquisition, or disposition of
18 dangerous drugs or dangerous devices shall be at all times during business hours open to
19 inspection by authorized officers of the law, and shall be preserved for at least three years from
20 the date of making. A current inventory shall be kept by every manufacturer, wholesaler,
21 pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian,
22 laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked
23 certificate, license, permit, registration, or exemption under Division 2 (commencing with
24 Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000)
25 of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or
26 dangerous devices.

27 “(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary
28 food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee,

1 for maintaining the records and inventory described in this section.”

2 9. Section 4113, subdivision (b) states:

3 “The pharmacist-in-charge shall be responsible for a pharmacy’s compliance with
4 all state and federal laws and regulations pertaining to the practice of pharmacy.”

5 10. Section 4160, subdivision (a) states:

6 “No person shall act as a wholesaler of any dangerous drug or dangerous device
7 unless he or she has obtained a license from the board. Upon approval by the board and the
8 payment of the required fee, the board shall issue a license to the applicant.”

9 11. Section 4332 states:

10 “Any person who fails, neglects, or refuses to maintain the records required by
11 Section 4081 or who when called upon by an authorized officer or a member of the Board, fails,
12 neglects, or refuses to produce or provide the records within a reasonable time, or who willfully
13 produces or furnishes records that are false, is guilty of a misdemeanor.”

14 12. Section 4380 provides, in pertinent part, that the resale, by any person, of
15 drugs acquired at preferentially low prices permitted under federal law only because of the
16 Nonprofit Institutions Act (15 U.S.C. Sec.13c) is prohibited.

17 13. California Code of Regulations, title 16, section 1718 states:

18 “Current Inventory” as used in Sections 4081 and 4332 of the Business and
19 Professions Code shall be considered to include complete accountability for all dangerous drugs
20 handled by every licensee enumerated in Sections 4081 and 4332. The controlled substances
21 inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon
22 request for at least 3 years after the date of inventory.”

23 14. California Code of Regulations, title 16, section 1709.1 provides, in
24 pertinent part, that the pharmacist-in-charge of a pharmacy shall be employed at that location and
25 shall have responsibility for the daily operation of the pharmacy.

26 15. Section 125.3 states, in pertinent part, that the Board may request the
27 administrative law judge to direct a licensee found to have committed a violation or violations
28 of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and

1 enforcement of the case.

2 FIRST CAUSE FOR DISCIPLINE

3 (Failure to Produce Records)

4 16. Respondents and each of them are subject to disciplinary action under
5 sections 4301(g), 4301(j), 4081(a), 4081(b), and 4332 of the Code, in conjunction with California
6 Code of Regulations, title 16, section 1718, for unprofessional conduct, in that Respondents
7 failed to produce the records of acquisition and disposition on June 16, 1999, during normal
8 business hours when demanded by a Board inspector. Specifically, Respondents failed to
9 provide complete records in a timely manner, in that Respondents provided only acquisition
10 records for an amount of \$485,164.71 in dangerous drugs for the audit period of January 1
11 through June 16, 1999, when Respondents had purchased \$6,968,612.84 in dangerous drugs.

12 SECOND CAUSE FOR DISCIPLINE

13 (Violated Federal Prescription Drug Marketing Act)

14 17. Respondents and each of them are subject to disciplinary action under
15 sections 4301 and 4380 of the Code, for unprofessional conduct, in that Respondents purchased
16 millions of dollars of drugs at preferentially low prices for the use of eligible non-profit
17 institutions and their patients. Respondents then knowingly and intentionally distributed them to
18 unknown recipients for their use, for other than the intended and legal purpose, under the
19 circumstances and at prices that took unfair advantage of competing pharmacies.

20 THIRD CAUSE FOR DISCIPLINE

21 (Wholesaling Without a License)

22 18. Respondents and each of them are subject to disciplinary action under
23 section 4160 and of the Code, for unprofessional conduct, in that Respondents sold dangerous
24 drugs to Montana Pharmacy Services, Inc., in Kalispell, Montana for the use of that pharmacy, in
25 the amount of \$6,590,117.02, between January 11, 1999 and June 28, 1999, without being
26 licensed to do so.

27 //

28 //

1 FOURTH CAUSE FOR DISCIPLINE

2 (Unprofessional Conduct)

3 19. Respondents and each of them are subject to disciplinary action under
4 sections 4301(f) and (o) of the Code, for unprofessional conduct, in that Respondents violated the
5 provisions of the state and federal laws and regulations governing pharmacy, as more full set
6 forth in paragraphs 16 through 18 above.

7 PRAYER

8 WHEREFORE, Complainant requests that a hearing be held on the matters herein
9 alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- 10 1. Revoking or suspending Original Pharmacy Permit No. PHY 43143,
11 issued to R & W Pharmacy Services, Inc.;
- 12 2. Revoking or suspending Original Pharmacist License No. RPH 30997,
13 issued to Arthur Howard Berger;
- 14 3. Ordering R & W Pharmacy Services, Inc. and Arthur Berger to pay the
15 Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,
16 pursuant to Business and Professions Code section 125.3;
- 17 4. Taking such other and further action as deemed necessary and proper.

18 DATED: 12/16/03

19 P. J. Harris
20 PATRICIA F. HARRIS
21 Executive Officer
22 Board of Pharmacy
23 Department of Consumer Affairs
24 State of California
25 Complainant

26 03583110-LA2000AD0169

27 jz

BILL LOCKYER, Attorney General
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A C C U S A T I O N

Original Pharmacy Permit No. PHY 43143

And

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15 Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,
16 pursuant to Business and Professions Code section 125.3;

17 4. Taking such other and further action as deemed necessary and proper.

18 DATED: 9/29/03

19 P. F. Harris

20 PATRICIA F. HARRIS

21 Executive Officer

22 Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant

23 03583110-LA2000AD0169

24 jz